

REMARKS

The Office Action of October 23, 2007, has been received and reviewed.

Claims 1, 4-18, 50, and 53-78 were previously pending and under consideration in the above-referenced application, each standing rejected.

Claims 9, 10, 13, and 17 have been canceled without prejudice or disclaimer.

Reconsideration of the above-referenced application is respectfully requested.

Claim Objections

Claims 9, 12, 15, 58, 61, 64, and 68 have been objected to for purportedly reciting Markush type species.

M.P.E.P. §2173.05(h) states “Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims.

Claim 9 has been canceled without prejudice or disclaimer.

It should be readily apparent from the language of claims 12, 15, 58, 61, 64, and 68 that the elements that are further defined by these claims are not strictly limited to the items that have been listed in the claims, as would occur in a Markush group. Rather, by their plain language, these claims recite various alternatives that must be present, without limiting the additional presence of other items within the elements that are limited by claims 12, 15, 58, 61, 64, and 68.

As none of claims 12, 15, 58, 61, 64, or 68 presents any uncertainty or ambiguity as to its scope, the objections to these claims should be withdrawn.

Claim 75 has been revised to address the Office’s objection to use of the phrases “a lysine” and “an arginine.” As is apparent from the Office’s objection, these revisions do not in any way narrow the scope of claim 75.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1, 4-18, 50, 53-67, and 69-73 have been rejected under the second paragraph of 35 U.S.C. § 112 for reciting subject matter that is purportedly indefinite. It is believed that the revisions to independent claims 1 and 50 and to claims 68, 69, 77, and 78 address the issues that have been presented by the Office without narrowing the scope of any of these claims or any

claim depending therefrom. Accordingly, withdrawal of the 35 U.S.C. § 112, second paragraph, rejections of claims 1, 4-18, 50, 53-67, and 69-73 is respectfully requested.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1, 4-8, 10-18, 50, 53-57, and 59-67 have been rejected for allegedly failing to comply with the written description requirement of the first paragraph of 35 U.S.C. § 112.

Basically, the Office has asserted that, by merely claiming compositions that include transfer factor, “[t]he claims are essentially of limitless breadth.” Office Action, page 5.

That is not true. The claims have very specific requirements that address an admittedly broad, but more complete, approach to treating cardiovascular disorders. The inclusion of transfer factor in compositions that also include the other components recited in each of the pending claims is itself unique, regardless of whether the transfer factor is non-specific, or is specific for any particular antigen.

In any event, each of independent claims 1, 50, and 68 is drawn to a composition that includes transfer factor that is specific for one or more of five listed pathogens.

For these reasons, it is respectfully submitted that each of claims 1, 4-8, 10-18, 50, 53-57, and 59-67 is drawn to subject matter that complies with the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, withdrawal of the 35 U.S.C. § 112, first paragraph, rejections of claims 1, 4-8, 10-18, 50, 53-57, and 59-67 is respectfully requested.

Rejections under 35 U.S.C. § 103(a)

Claims 1, 4-17, 50, 53-66, and 68-78 are rejected under 35 U.S.C. § 103(a).

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 82 USPQ2d 1396 (2007). The Office must also establish that one of ordinary skill in the art would have had a reasonable expectation of success that the purported modification or combination of reference teachings

would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). There must also be “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR* at 1396. That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant’s disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

Ramaekers in View of Rath, Tentolouris, Cholesterol-Lowering Drugs, Focant, or Kirkpatrick

Claims 1, 7-15, 17, 50, 56-64, 66, and 72-78 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over the subject matter taught in U.S. Patent 6,506,413 to Ramaekers (hereinafter “Ramaekers”), in view of teachings from U.S. Patent 5,650,418 to Rath et al. (hereinafter “Rath”); Tentolouris et al., “*L-Arginine in coronary atherosclerosis*,” *International Journal of Cardiology*, 75 (2000), pp. 123-128 (hereinafter “Tentolouris”); “Cholesterol-Lowering Drugs” (<http://www.americanheart.org/presenter.jhtml?identifier=4510>) (3 pages) (hereinafter “Cholesterol-Lowering Drugs”); Focant et al., “The Effect of Vitamin E Supplementation of Cow Diets Containing Rapeseed and Linseed on the Prevention of Milk Fat Oxidation,” *Journal of Dairy Science*, 81 (1998) pp. 1095-1101 (Abstract) (hereinafter “Focant”); Gordon, “*Cardiovascular Research*,” *Explore* (1999) (hereinafter “Gordon”), http://www.explorepub.com/articles/heart_disease.html (11 pages) (hereinafter “Gordon”); or Kirkpatrick, “*Properties and Activities of Transfer Factor*,” *Journal of Allergy and Clinical Immunology*, 55(6) (1975), pp. 411-421 (Abstract) (hereinafter “Kirkpatrick”).

Claims 9, 10, 13, and 15 have been canceled without prejudice or disclaimer, rendering the rejections of these claims moot.

The teachings of Ramaekers are directed to compositions for treating various ailments in animals. Each of the disclosed compositions includes either transfer factor and a lactic acid-forming bacteria or transfer factor, zinc, and an essential fatty acid. Ramaekers does not

teach or suggest that any of the disclosed compositions is useful for treating a cardiovascular disorder.

Rath teaches compositions that are useful for treating cardiovascular disorders. The essential components of such compositions are ascorbate, nicotinic acid, and lysine, which are "preferentially present in a ratio of 8:1:1."

The teachings of Tentolouris relate to the benefits of L-arginine. Specifically, Tentolouris teaches that nitric oxide, which is formed as the N-guadino terminal end of L-arginine, is useful in improving blood flow through coronary arteries.

Cholesterol-Lowering Drugs discusses various drugs that are useful in lowering blood cholesterol levels, particularly in patients who are at risk for coronary heart disease.

Focant teaches that oxidation of the milk of cows that eat rapeseed and linseed may be reduced by supplementation with vitamin E. The teachings of Focant have nothing to do with compositions for treating cardiovascular disorders.

The teachings of Gordon relate to compositions that apparently include non-specific transfer factor in combination with a large number of other components, including components that lower circulating immune complexes, components that lower fibrinogen levels, components that lower elevated C-reactive proteins, and (heavy metal) detoxification/chelation components.

Kirkpatrick teaches that transfer factor has "direct effects on inflammatory sites."

It is respectfully submitted that the teachings of Ramaekers, in combination with any of Rath, Tentolouris, Cholesterol-Lowering Drugs, Focant, Gordon, or Kirkpatrick do not support a *prima facie* case of obviousness against any of claims 1, 7, 8, 11, 12, 14, 17, 50, 56-64, 66, or 72-78 for at least two reasons.

First, none of the references that have been relied upon in rejecting claims 1, 7, 8, 11, 12, 14, 17, 50, 56-64, and 66 teaches or suggests a composition that includes transfer factor that is specific for at least one of herpes simplex virus type I, herpes simplex virus type II, cytomegalovirus, *Chlamydia pneumoniae*, and *Helicobacter pylori*, as is required of the compositions recited in amended independent claims 1 and 50. In this regard, the teachings and suggestions of Ramaekers are limited to the use of transfer factor to treat animal pathogens, the teachings of Kirkpatrick are limited to a broad discussion of transfer factor without any teaching

or suggestion regarding specificity, and the teachings of Gordon are limited to transfer factor that “may improve resistance to Herpes, CMV, Chlamydia, and Helicobacter [sic]” without teaching or suggesting that the transfer factor of the disclosed composition may be specific for any of these pathogens.

Second, with respect to the subject matter recited in amended independent claims 1 and 50 and their respective dependent claims, it is respectfully submitted that there would have been no apparent reason for one of ordinary skill in the art to combine teachings from Ramaekers with teachings from any of Rath, Tentolouris, Cholesterol-Lowering Drugs, Focant, Gordon, or Kirkpatrick in the manner that has been asserted. This is because amended independent claims 1, 50, and 68 recite compositions that consist essentially of transfer factor and other listed elements. None of those elements includes a lactic acid-forming bacteria or zinc and an essential fatty acid, as are present in each of the compositions disclosed by Ramaekers. Additionally, Rath, Cholesterol-Lowering Drugs, and Gordon teach compositions that include a number of essential elements that are not recited in amended independent claim 1 or amended independent claim 50.

As for the subject matter to which independent claim 72 and its dependent claims 73-78 are drawn, none of Ramaekers, Rath, Tentolouris, Cholesterol-Lowering Drugs, Focant, Gordon, or Kirkpatrick, taken alone or in any combination, teaches or suggests a composition that includes a preparation including transfer factor and vitamin C in the same amounts.

Nor has the Office presented any apparent reason that one of ordinary skill in the art would have been motivated to modify teachings from Ramaekers or to combine teachings from Ramaekers with teachings from any of the other cited references to develop such a composition.

Ramaekers, Tentolouris, and Tokoro

Claims 4-6, 53-55, 68, 70, and 71 stand rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is allegedly unpatentable over the teachings of Ramaekers, in view of teachings from Tentolouris and, further, in view of the subject matter taught in U.S. Patent 5,080,895 to Tokoro (hereinafter “Tokoro”).

It is respectfully submitted that claims 4-6 are allowable, among other reasons, for depending directly or indirectly from independent claim 1, which is allowable.

Each of claims 53-55 is allowable, among other reasons, for depending directly or indirectly from independent claim 50, which is allowable.

Furthermore, the teachings of Ramaekers, Tentolouris, and Tokoro do not support a *prima facie* case of obviousness against any of claims 4-6, 53-55, 68, 70, or 71.

In this regard, it is respectfully submitted that, as the compositions disclosed in Ramaekers include essential components (e.g., lactic acid-forming bacteria or zinc and an essential fatty acid) in addition to those of the compositions to which claims 4-6, 53-55, 68, 70, and 71 are directed, there would have been no motivation for one of ordinary skill in the art to modify the teachings of Ramakers or to combine them with teachings from Tentolouris and Tokoro to develop the compositions that are recited in these claims.

It is further submitted that none of Ramaekers, Tentolouris, or Tokoro teaches or suggests a composition that includes non-mammalian transfer factor. Although Tokoro has been relied upon in this respect, Tokoro does not actually include any teaching or suggestion that transfer factor may be obtained from chickens eggs. Rather, the teachings of Tokoro are limited to a "transfer factor-like" substance, which is known in the art to be different from transfer factor. See, e.g., Dunnick, W., et al., "Lack of Antigen Fragments in Guinea Pig Transfer Factor-like Activity, Clin. Immunol. and Immunopathol. 17: 55-65 (1980), at page 65. Furthermore, it is well known in the art that transfer factor-like substances are incapable of causing the immune system of a treated animal to elicit a specific response (i.e., a response to a particular antigen), while transfer factor can elicit a specific response from the immune system of a treated animal.

Therefore, it is respectfully submitted that each of claims 4-6, 53-55, 68, 70, and 71 is directed to subject matter that is allowable over the subject matter taught by Ramaekers, Tentolouris, and Tokoro.

Ramaekers in View of Singh

Claims 16 and 65 stand rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is purportedly unpatentable over the subject matter taught in Ramaekers, in view of teachings from Singh et al., "Coenzyme Q in cardiovascular disease," Assoc. Physicians India. (Mar 1998) 46(3):299-306 (Abstract) (hereinafter "Singh").

Claims 16 and 65 are allowable, among other reasons, for respectively depending directly from independent claims 1 and 50, which are allowable.

Ramaekers, Tentolouris, and Pearson

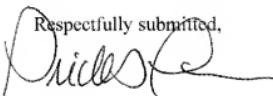
Claim 69 stands rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over that taught in Ramaekers, in view of teachings from Tentolouris, in light of the subject matter taught in U.S. Patent 6,693,094 to Pearson et al. (hereinafter "Pearson").

Claim 69 is allowable, among other reasons, for depending from independent claim 68, which is allowable.

For these reasons, withdrawal of the 35 U.S.C. § 103(a) rejections of claims 1, 4-8, 10-12, 14-16, 50, 53-66, and 68-78 is respectfully solicited, as is the allowance of each of these claims.

CONCLUSION

It is respectfully submitted that each of claims 1, 4-8, 10-12, 14-16, 50, 53-66, and 68-78 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,


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